Atty. Dkt. No.: 5838-01000

Response To Office Action Mailed February 14, 2003

A. <u>Pending Claims</u>

Claims 15-19 and 25, 27-38, 40-50, 52-62, and 64-86 are currently pending. Claims 26, 39, 51, and 63 have been cancelled. Claims 28, 29, 32, 34-37, 41, 42, 45, 47-50, 53, 54, 57, 59-62, 65, 66, 69, and 71-74 have been amended. Claims 75-86 are new.

B. Petition to Correct Inventors Name

The Examiner rejected the petition to correct the inventors name under 37 CFR 1.48(a). The Examiner stated:

An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted. Specifically, the submitted declaration lacks a date for one inventor.

In response to the Examiners rejection a new Declaration and Power of Attorney is provided in an accompanying document.

C. The Claims Are Not Anticipated By Martin Pursuant To 35 U.S.C. § 102(e)

The Examiner rejected claims 18, 51-55, 59, and 60 under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,162,537 to Martin et al. ("Martin"). Applicant respectfully disagrees with these rejections.

In item 2 of the Office Action, the Examiner states:

Martin et al. discloses a ventricular patch (lines 34-47 of col. 12) having a combination of fibers that are treated with radiopaque dyes before or after extrusion (see line 61 of col. 7 through line 58 of col. 8, lines 7-13 of col. 9, and line 59 of col. 9 through line 15 of col. 10). The second fiber may be polyester (lines 12-31 of col. 7) and the first component may be collagen (lines 25-41 of col. 6).

Claim 18 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of equally spaced concentric circles having different diameters." At least the above-quoted features of the claim, in combination with other features of the claim, do not appear to be taught or suggested by the cited art.

Martin discloses in column 8, lines 4-8:

The incorporation of pharmaceutically active agents may be desired to augment the local healing response to the fiber to provide local or systemic delivery of agents which improve device performance and clinical outcome.

In addition, Martin discloses (column 8, lines 50-51): "The additives can improve stability during fabric processing conditions and/or fiber properties in the body." Martin does not appear to teach or suggest a plurality of markings couple to the sheet configured in distinct patterns for post operatively evaluating movement of the patch. Applicant submits that the combination of features in claim 18 and the claims dependent thereon are neither taught nor suggested by the cited art. Applicant respectfully requests removal of the rejection of claim 18 and claims dependent thereon.

Applicant believes many of the claims dependent on claim 18 may be separately patentable. For example, amended claim 53 recites, in part: "wherein the markings are

radiopaque." At least the above-quoted feature of the claim, in combination with other features of the claim, does not appear to be taught or suggested by the cited art.

Amended claim 54 recites, in part: "wherein the markings are imprinted on the material with radiopaque ink." At least the above-quoted feature of the claim, in combination with other features of the claim, does not appear to be taught or suggested by the cited art.

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Claim 55 recites, in part: "wherein the biocompatible material is formed of threads produced by co-extruding the material with radiopaque polymeric material." At least the above-quoted feature of the claim, in combination with other features of the claim, does not appear to be taught or suggested by the cited art.

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Amended claim 59 recites, in part: "wherein the markings are MRI scan sensitive." At least the above-quoted feature of the claim, in combination with other features of the claim, does not appear to be taught or suggested by the cited art.

D. The Claims Are Not Anticipated By Alt Pursuant To 35 U.S.C. § 102(b)

The Examiner rejected claims 15, 17, 19, 25, 28, 29, 32, 34-36, 38, 41, 42, 45, 47-49, 65, 66, 69, and 71-73 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,411,527 to Alt ("Alt"). Applicant respectfully disagrees with these rejections.

In item 3 of the Office Action, the Examiner states:

Alt discloses a ventricular patch in figure 2 comprising metal thread markings or ink markings on a biocompatible surface in either a grid, parallel lines, or lines radiating from a point. See lines 42-52 of col. 10, lines 4-22 of col. 11, line 61 of col. 11 through line 2 of col. 12, lines 5-16 of col. 13, and lines 11-

27 of col. 16.

Claim 15 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a plurality of equally spaced substantially parallel lines." Claim 17 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a uniform grid of horizontal and vertical lines." Claim 19 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of line radiating from a single point." At least the above-quoted features of the claims, in combination with other features of the claims, do not appear to be taught or suggested by the cited art.

Applicant discloses in the specification in paragraph 0071:

In order to be useful, the markings must be arranged in a pattern that allows post operative evaluation. One such pattern is a series of equally spaced substantially parallel lines as illustrated in Fig. 3c. The distance between these parallel lines may be in standard units, such as 1 centimeter. Another pattern could be in the form of concentric circles, as illustrated in Fig. 3d. Yet, another pattern could be a series of lines radiating from a single point at, for instance, a set angle apart. Such a pattern is illustrated in Fig. 3e.

Alt discloses in column 16, lines 11-18:

For precise placement of a polymer fiber electrode by X-ray, fluoroscopy or endoscopy, the fibers may be interspersed with fibers composed of material opaque to radiation of the type employed for viewing the progress of the implantation procedure from a point external to the body. The opaque fibers or

strands 8 are interposed among the polymer fibers 2 as shown in the cross-sectional view of FIG. 4.

Applicant submits that Alt does not appear to teach, disclose, or suggest a plurality of markings configured in distinct patterns for post operatively evaluating movement of a patch. Applicant respectfully requests removal of the rejection of claims 15, 17, 19, and claims dependent thereon.

Applicant believes many of the claims dependent on claims 15, 17, and 19 may be separately patentable. For example, claims 25, 38, and 66 recites, in part: "wherein the movement of the patch is measured along a longitudinal axis and a transverse axis of the patch." At least the above-quoted feature of the claims, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

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Amended claims 29, 42, and 66 recites, in part: "wherein the markings are imprinted on the material with radiopaque ink." At least the above-quoted feature of the claims, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

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Amended claims 34, 47, and 71 recites, in part: "wherein the markings are MRI scan sensitive." At least the above-quoted feature of the claims, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

E. The Claims Are Not Anticipated By Milijasevic Pursuant To 35 U.S.C. § 102(b)

The Examiner rejected claims 18, 19, 51, 53, 57-61, 63, 65, and 69-73 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,938,231 to Milijasevic ("Milijasevic"). Applicant respectfully disagrees with these rejections.

In item 4 of the Office Action, the Examiner states:

Milijasevic discloses a ventricular patch in figures 2 and 10 having radiopaque threads (platinum or stainless steel threads) enveloped by a polyester mesh. (see lines 34-62 of col. 3 and line 45 of col. 5 through line 25 of col. 6).

Claim 18 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of equally spaced concentric circles having different diameters." Claim 19 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of line radiating from a single point." At least the above-quoted features of the claims, in combination with other features of the claims, do not appear to be taught or suggested by the cited art.

Milijasevic discloses in column 3, lines 42-43: "Sheet 20 is preferably formed from a thin, fine woven mesh of a conductive material." In addition, Milijasevic discloses (column 3, lines 63-68): "the electrically conductive flexible sheet includes a plurality of elongated slits arranged in a pattern. Importantly, a part of an interior portion of the sheet defined by the pattern is flexibly movable in a direction perpendicular to the plane of the sheet." Milijasevic does not appear to teach or suggest a plurality of markings coupled to the sheet configured in distinct patterns for post operatively evaluating movement of the patch. Applicant submits that the combination of features in claims 18, 19, and the claims dependent thereon are neither taught nor suggested by the cited art. Applicant respectfully requests removal of the rejection of claims 18, 19, and claims dependent thereon.

F. The Claim is Not Obvious Over Alt Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claim 16 under 35 U.S.C. 103(a) as obvious over Alt. Applicant

respectfully disagrees with these rejections.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). For at least the reasons in Section D above, Applicant submits that the cited art does not appear to teach

or suggest the combination of features in claim 16. Applicant requests removal of the

obviousness rejection of the claim.

G. The Claims Are Not Obvious Over Alt Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claims 33, 37, 46, 50, 70, and 74 under 35 U.S.C. 103(a) as

obvious over Alt. Applicant respectfully disagrees with these rejections.

For at least the reasons in Section D above, Applicant submits that Alt does not appear to

teach or suggest the combination of features in claims 33, 37, 46, 50, 70, and 74. Applicant

requests removal of the obviousness rejection of the claims.

H. The Claims Are Not Obvious Over Milijasevic Pursuant To 35 U.S.C. § 103(a)

The Examiner rejected claims 54, 62, 66, and 74 under 35 U.S.C. 103(a) as obvious over

Milijasevic. Applicant respectfully disagrees with these rejections.

For at least the reasons in Section E above, Applicant submits that Alt does not appear to

teach or suggest the combination of features in claims 54, 62, 66, and 74. Applicant requests

removal of the obviousness rejection of the claims.

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I. The Claims Are Not Obvious Over Alt In View of Milijasevic Pursuant To 35 U.S.C.
§ 103(a)

The Examiner rejected claims 26, 39, and 63 under 35 U.S.C. 103(a) as obvious over Alt in view of Milijasevic.

Claims 26, 39, and 63 have been canceled.

J. The Claims Are Not Obvious Over Milijasevic In View of Zhong Pursuant To 35
U.S.C. § 103(a)

The Examiner rejected claims 55, 56, 67, and 68 under 35 U.S.C. 103(a) as obvious over Milijasevic in view of U.S. Patent No. 6,368,356 to Zhong et al. ("Zhong"). Applicant respectfully disagrees with these rejections.

For at least the reasons in Section E above, Applicant submits that Alt in view of Zhong does not appear to teach or suggest the combination of features in claims 55, 56, 67, and 68.

Applicant requests removal of the obviousness rejection of the claims.

K. The Claims Are Not Obvious Over Martin In View of Zhong Pursuant To 35 U.S.C.
§ 103(a)

The Examiner rejected claim 56 under 35 U.S.C. 103(a) as obvious over Martin in view of Zhong. Applicant respectfully disagrees with these rejections.

For at least the reasons in Section C above, Applicant submits that Martin in view of

Zhong does not appear to teach or suggest the combination of features in claim 56. Applicant requests removal of the obviousness rejection of the claims.

L. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

A Fee Authorization is enclosed to cover fees for additional claims. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any further fees are required, please charge those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-01000/EBM.

Respectfully submitted,

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Date: <u>5-13-03</u>

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Marked-Up Version of Amendments Submitted With Amendment; Response To Office Action Mailed February 14, 2003

- 28. (Amended) The ventricular patch of claim 15, wherein the markings are radio-paque.
- 29. (Amended) The ventricular patch of claim 28, wherein at least some of the markings are imprinted on the material with radiopaque ink.
- 32. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are metal threads.
- 34. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are MRI scan sensitive.
- 35. (Amended) The ventricular patch of claim 15, wherein <u>at least some of the markings are</u> coupled to the material using mechanical means.
- 36. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are coupled to the material using adhesive means.
- 37. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are imprinted by ion deposition.
- 41. (Amended) The ventricular patch of claim 17, wherein the markings are radio-paque.
- 42. (Amended) The ventricular patch of claim 28, wherein at least some of the markings are imprinted on the material with radiopaque ink.
- 45. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are metal threads.

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47. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are MRI scan sensitive.

- 48. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are coupled to the material using mechanical means.
- 49. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are coupled to the material using adhesive means.
- 50. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are imprinted by ion deposition.
- 53. (Amended) The ventricular patch of claim 18, wherein the markings are radio-paque.
- 54. (Amended) The ventricular patch of claim 28, wherein at least some of the markings are imprinted on the material with radiopaque ink.
- 57. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are metal threads.
- 59. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are MRI scan sensitive.
- 60. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are coupled to the material using mechanical means.
- 61. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are coupled to the material using adhesive means.
- 62. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are imprinted by ion deposition.

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- 65. (Amended) The ventricular patch of claim 19, wherein the markings are radio-paque.
- 66. (Amended) The ventricular patch of claim 28, wherein at least some of the markings are imprinted on the material with radiopaque ink.
- 69. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are metal threads.
- 71. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are MRI scan sensitive.
- 72. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are coupled to the material using mechanical means.
- 73. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are coupled to the material using adhesive means.
- 74. (Amended) The ventricular patch of claim 15, wherein at least some of the markings are imprinted by ion deposition.